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(54) BONE AND JOINT PROSTHESIS

(71) We, HOWMEDICA INC, a Corporation organized under the laws of the State of Delaware, United States of America, of 235 East 42nd Street, New York, State of New York, United States of America, do hereby declare the invention, for which we pray that a Patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a bone and joint prosthesis and more particularly to a shoulder prosthesis.

Prosthesis used for joining and replacing human bones and joints necessitate a means for conveniently and reliably locking bones and joints securely together in an articulating or a nonarticulating manner. Various conventional mechanical locking devices, such as screw threads and collets, have been used, but they have the problem of releasing under prolonged service or might not be convenient for installation and removal in surgery. The present invention provides a simple and economical prosthesis for locking joints and bones together, and more particularly to such a prosthesis which facilitates the installation and removal of articulating prosthetic joints in the human body.

In accordance with the present invention there is provided a prosthetic device comprising a cup-shaped component having a cup and a fixation stem extending from the base of the cup for attachment to a bony portion of the body, a ball component having a fixation rod member connected to the ball component for attachment to another bony portion of the body, a two-part lining insert having outer dimensions adapted to engage within the cup, the lining insert having an inner cavity adapted to embrace the ball component, an internally flanged locking ring which engages the outer rim of the cup, the internally flanged locking ring having an aperture through which the ball component is freely inserted, a circular groove about the rim of the cup adapted to snugly receive the internal flange of the locking ring, and a retaining shoulder within the locking ring which retains the lining insert and ball component within the cup.

In practice, the ball (scapular) component is rotatably held within the cup of the cup-shaped (humeral) component between the parts of the two-part plastic lining insert, which are locked within the cup by the locking ring which, by virtue of its resilience, snaps into the external circular groove on the rim of the cup. The rim and locking ring may have mutually engaging bevelled edges which firmly engage each other. The two part lining insert is, for example, made of ultra high molecular weight polyethylene, while the humeral and intracancellar components are, for example, made of a biocompatible metal, which lends strength and self-lubrication to the joint.

The invention will be more particularly described with reference to the accompanying drawings wherein similar reference characters refer to similar parts and in which:—

Figure 1 is a front view in elevation partially broken away in cross-section of a scapular prosthesis with human body portions, with the opposite limit position shown in phantom outline;

Figure 2 is an exploded view of all of the components of the prosthesis shown in Figure 1 with a portion of the ball component broken away;

Figure 3 is a right side elevational view of the humeral socket portion of the prosthesis shown in Figures 1 and 2;

Figure 4 is a cross-section through line 4-4 of Figure 2;

Figure 5 is a right side view of the fixation portion of the intracancellar component of the

prosthesis shown in Figure 1;

Figure 6 is a top plan view of the locking ring of the prosthesis shown in Figures 1 and 2;

Figure 7 is a top plan view of the liner inserts of the prosthesis shown in Figures 1 and 2; and

Figure 8 is a top plan view looking down at the cup cavity of the humeral component shown in Figure 3.

The preferred embodiment illustrated in Figure 1 is a scapular articulating joint prosthesis 10 including a humeral component 12 having a cup 14. Humeral component 12 is attached to the top of a humerus 16 by insertion of tapered stem 18 having a substantially triangular cross-section as shown in Figure 4, into the intramedullary canal 20 of the humerus. The humeral or socketed component 12 is made of a biocompatible metal such as cast "Vitallium" alloy. The centreline 15 of the cup 14 and the centreline 19 of the stem 18 are disposed at an angle B for example 30°, relative to each other. The left (dorsal) side of the stem 18 extends substantially tangentially across the outer surface of the cup 14 so that the surface of the stem merges smoothly with the outside surface of the cup.

"Vitallium" is the trademark of Howmedica Inc., for a special cobalt-chromium alloy developed and used for cast partial and full dentures, and for internal application by surgeons. Cobalt and chromium constitute over 90% of its composition. Sp.gr. 8.29; tensile strength, 95,000 lb/sq.in.min.: 2% offset yield strength 65,000 lb/sq.in.min.: Reduction of area 8% min.; elongation, 8% min. modulus of elasticity, 30,000,000—32,000,000 lb/sq.in. When polished, it is exceedingly smooth and permanently lustrous. Its outstanding qualities are clinical inertness in relation to living tissues and a high degree of resistance to corrosion.

Figure 2 shows the separate components of the prosthesis 10, which are shown assembled in Figure 1. A ball or scapular component 22 is also made, for example, of a biocompatible metal such as cast "vitallium" alloy, and includes a polished spherical ball 24 connected to a fixation plate 26 by a neck 28 which is disposed at an angle of 15° with respect to the plate. Fixation rods 30, 32 and 34 extend at strategic angles from the fixation plate 26, as shown in Figures 1 and 5. The length of the rods, 30, 32 and 34 are, for example 15, 10 and 20 mm. The fixation means may be diversely shaped and adapted for the particular portion of the body to which ball component 22 is to be attached. The ball 24 is rotatably locked to the humeral component 12 by engagement between a two-part lining insert 36 made, for example, of high density polyethylene and more particularly of ultra-high molecular weight polyethylene, which has excellent strength and self-lubricating properties with respect to the cast "Vitallium" alloy ball 22. The limits of movement about the ball's centre are controlled by contact of the fixation plate 26 with the locking ring 38. In the particular form of the invention shown in Figure 1, that is the angle A in the vertical plane through the axes of both components.

Lining insert 36 embraces the ball 24 and then is locked within cup 14 under a shoulder 37 of a locking ring 38, shown in Figure 6, which is snap fitted as shown in Figure 1 over the outer rim 40 of cup 14. An inwardly directed flange 42 of the cover ring 38 is inserted into and locked within a circular groove 44 about the outer rim of the cup 14. The inner bevelled surface 46 within the ring 38 has an angle of 31°, and closely engages a contacting bevelled rim 48 about the outer edge of the cup 14, which rim 48 has an angle of 33°. The angular variation between the bevelled surface 46 and the bevelled rim 48 ensures a tight lock when the flange 42 of ring 38 is snapped into the circular groove 44. The locking ring 38 is conveniently formed of a tough and resilient polyethylene, which is biocompatible as well as strong, tough, resilient and durable.

The socket cavity 49 defined by the inner surface of the two-part lining insert 36 is such as to enclose more than half of the ball 24, thus securely maintaining the ball component 22 securely engaged within the humeral component 12. For the joint 10 the engagement is articulating, which allows mutual rotation between limit positions in the plane shown in Figure 1 over an angle A, for example, of 90°. Similar angles of rotation are afforded in other planes. The degree of rotation depends upon the type of joint such as shoulder, hip or elbow and in some instances no articulation is necessary and the joint is substantially non-rotating.

Typical dimensions of the principal components of joint 10 are as follows:

Component	*Millimetres*
Ball 24 and socket cavity 49 radius	11 mm
Inside radius of cup 14 and outer radius of lining insert	17.5 mm
Depth of cup 14 and lining insert 36	21.4 mm
Thickness of cup wall	3.9 mm
Outer diameter of locking ring 38	42.5 mm
Inside diameter of locking flanges 42 at bottom of locking ring.	36 mm
Thickness of locking ring 38	2.69 mm
Distance between locking flange bevels 46 and inside shoulder	2.0 mm

Angle of bevel within locking ring and on rim of cup	31° 33°
Overall height of ring 38	7.15 mm
Length of stem 12	40 mm
Width of stem tapers to an end width of about	6.4 mm
Angle of stem rear wall with respect to stem centreline	3°
The cross-section of the stem is triangular as shown in Figure 1 with chamfered corners and width at section cutting line 4 is	4.4 mm
Angle of ball stem 28 with respect to fixation plate 26	15°

The prosthesis 10 is assembled in the scapular portion in the body in the following manner. The metal humeral component 12 is inserted into the intramedullary canal of the humerus bone in the upper arm after proper preparation. The scapular component 22 is inserted into the intracancellar portion of the scapula (upper portion of the shoulder joint).

The ultra high molecular weight polyethylene locking ring 38 is placed over the ball of the scapular component with the locking flange 42 facing toward the open end of the humeral cup 14. The two parts of the polyethylene lining insert 36 are placed over the ball 24 of the scapula component and together partially encompass the ball. This is followed by placement of the assembly into the cup 14 of the metal humeral component 12. The polyethylene locking ring 38 is then pressed on to the outer rim of the humeral cup component to engage the flange 42 in the circular groove 44 provided therefor.

WHAT WE CLAIM IS:—

1. A prosthetic device comprising a cup-shaped component having a cup and a fixation stem extending from the base of the cup for attachment to a bony portion of the body, a ball component having a fixation rod member connected to the ball component for attachment to another bony portion of the body, a two-part lining insert having outer dimensions adapted to engage within the cup, the lining insert having an inner cavity adapted to embrace the ball component, an internally flanged locking ring which engages the outer rim of the cup, the internally flanged locking ring having an aperture through which the ball component is freely inserted, a circular groove about the rim of the cup adapted to snugly receive the internal flange of the locking ring, and a retaining shoulder within the locking ring which retains the lining insert and ball component within the cup.

2. A device according to claim 1, wherein the ball component is substantially spherical and the cavity within the insert liner encloses more than half of the ball component.

3. A device according to either one of claims 1 or 2, wherein the fixation stem of the cup-shaped component is adapted to be engaged within the intramedullar canal of the humerus, and the fixation rod member on the ball component is adapted to engage the intracancellar portion of the scapula.

4. A device according to any one of the preceding claims, wherein the two-part lining insert is formed of ultra high molecular weight polyethylene, and the cup-shaped and ball components are of biocompatible metal.

5. A device according to any one of the preceding claims, wherein the range of angular movement between the cup-shaped and ball components is 90°.

6. A device according to any one of the preceding claims wherein the cup and fixation stem attached thereto have centrelines which are disposed at an angle of 30° relative to each other.

7. A device according to claim 6, wherein one side of the fixation stem is substantially tangential to the outer surface of the cup.

8. A device according to any one of the preceding claims, wherein the fixation rod member comprises a fixation plate having a plurality of rods extending therefrom in a direction remote from the ball, the ball being attached to the side of the fixation plate opposite the fixation rods by a neck, and the neck being disposed at an angle of 15° with respect to the fixation plate.

9. A device according to claim 7, wherein three fixation rods extend from the fixation plate to lengths of 10, 15 and 20 mm.

10. A device according to any one of the preceding claims, wherein the fixation stem member is substantially triangular in cross-section.

11. A device according to any one of the preceding claims, wherein the rim of the cup and the corresponding surface of the locking ring are bevelled for close engagement therebetween.

12. A device according to claim 11, wherein the angle of bevel of the rim of the cup is slightly greater than the angle of bevel of said corresponding surface of the locking ring.

13. A device according to claim 12, wherein the rim is bevelled at an angle of 33° and the corresponding surface of the locking ring is bevelled at an angle of 31°.

14. A prosthetic device according to claim 1 and substantially as hereinbefore described with reference to the accompanying drawings.

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1 SHEET This drawing is a reproduction of the Original on a reduced scale

FIG.1

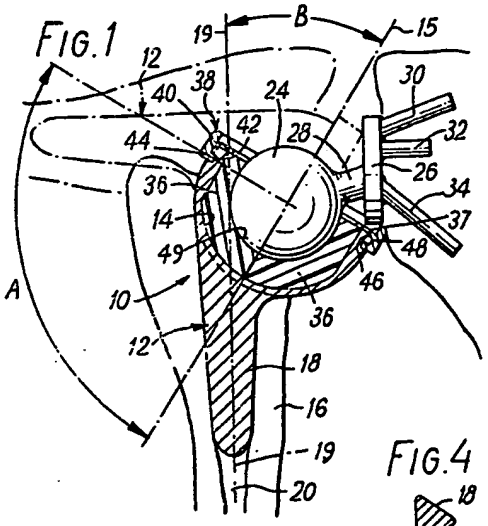

FIG.3

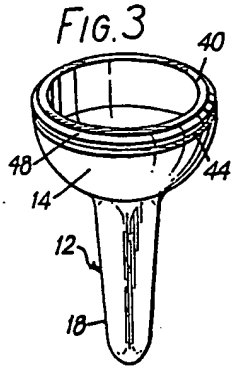

FIG.4

FIG.5

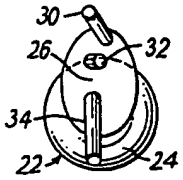

FIG.2

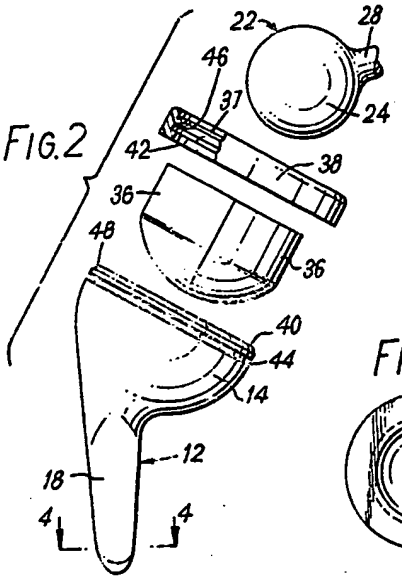

FIG.6

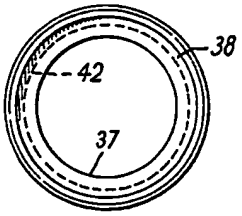

FIG.7

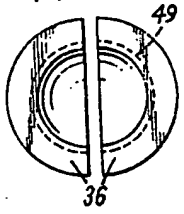

FIG.8